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#13

In re Application of :
Partha S. Banerjee et al :
Serial No.: 09/887,496 : PETITION DECISION
Filed: June 22, 2001 :
Attorney Docket No.: 7707 :

This is a decision on the petition under 37 CFR 1.144, filed June 17, 2002, to withdraw an improper restriction requirement. The delay in acting on this petition is regretted, however the petition was not correlated with the file for more than two months.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111. The examiner mailed a first Office action to applicants on January 7, 2002, setting forth a four way restriction requirement, as follows:

> Group I , claims 1-83, 87-89, 99-112 and 117-119, drawn to pharmaceutical compositions comprising formoterol and a steroidal anti-inflammatory agent;
> Group II, claims 84-86 and 94-98, drawn to a method of treating bronchial disorders using pharmaceutical compositions comprising formoterol and a steroidal anti-inflammatory agent;
> Group III, claims 93, 113-116 and 120-121, drawn to pharmaceutical compositions comprising formoterol, a steroidal anti-inflammatory agent and another active agent;
> Group IV, claims 90-92, drawn to a method of treating bronchial disorders using pharmaceutical compositions comprising formoterol, a steroidal anti-inflammatory agent and another active agent.

The examiner reasoned that Groups I and II and Groups III and IV were related as product and process of use and were distinct and separate inventions giving appropriate reasoning. The examiner also indicated that Groups I and II (sic III) and Groups III (sic II) and IV were unrelated as they had different modes of operation. The examiner required further an election of species for each component of the composition - formoterols, anti-inflammatories and the third active agent.

Applicants replied to the Office action on January 31, 2002, electing the claims of Group I with traverse and the species formoterol and fluticasaone or fluticasone proprionate. Applicants canceled claims 84-86, 90-92 and 94-98 (the claims of Groups II and IV). Applicants traversed the requirement on the basis that Groups I and III (and Groups II and IV) are related as combination and subcombination and the examiner had not demonstrated the required two way distinctness.

The examiner mailed a non-Final Office action to applicants on April 24, 2002. The examiner maintained the restriction requirement, making it Final, and replied to applicants' traversal. The examiner reasoned that the two groups (I and III) are distinct because they have different numbers of active ingredients and therefor different modes of operation. The examiner made the requirement Final. The examiner also rejected claims 63-72 under 35 U.S.C. 112, second paragraph for indefiniteness and claims 1-64, 69-83, 87-89, 99-112 and 117-119 as obvious under 35 U.S.C. 103(a) over Hochrainer et al in view of Bartow et al and PDR.

Applicants filed this petition on June 17, 2002. Applicants also filed a reply to the rest of the Office action on July 24, 2002, by amending several parts of the specification and claims 1, 63, 95 and 117, and arguing the rejections of record. The restriction requirement was again traversed and the petition referenced.

DISCUSSION

Applicants argue that the claims as grouped by the examiner are related as two sets of combination-subcombination claims and that the examiner has not met the requirement for restricting claims in this relationship by showing two-way distinctness. The examiner reasons, conversely that the related claims have different modes of operation.

A review of the claims shows that the claims of Group I all depend directly or indirectly on claim 1 (composition), 77 (nebulized composition), 78 (kit comprising the composition and nebulizer) or 117 (combination of solutions). These claims are based on combining formoterol and an anti-inflammatory agent as active ingredients to which may be added a number of other components, such as buffers, tonicity agents, etc. The claims of Group III all depend directly or indirectly from Claim 1 and are based on a combination of formoterol, an anti-inflammatory agent and a third component (agonists, antagonists, inhibitors, etc.) all of which are also considered to be active agents. Clearly the claims of Group III are a combination of the composition of Group I and an additional ingredient. Thus the claims of Group I are a subcombination of the claims of Group III. As noted by applicants, claims in this relationship can only be restricted from each other where the combination does not require the particulars of the subcombination for patentability and the subcombination can be shown to have utility by itself or in other and different relations.

By definition a subcombination has less that all of the elements of the combination. Here the subcombination does not have or require the third active component for patentability and has utility in and of itself, thus meeting the second requirement noted above for restriction. The converse, however, is not true; the combination does require the elements of the subcombination for patentability. Assuming that the subcombination is a patentable composition of matter, adding an additional active element to it to make a new composition of matter wherein each component

retains its identity, as in the subcombination, must also create a patentable composition based on the patentability of the subcombination. It is possible that the subcombination could be determined not to be patentable, but that the addition of the third component to the first two components creates a patentable composition. In this instance patentability of the combination would not be dependant on the subcombination as it is unpatentable. As applicants have elected the subcombination for prosecution consideration of the combination is required as the examiner has not yet shown that the combination does not depend on the subcombination for patentability. The examiner's argument that the compositions would have different modes of operation is inapposite as only compositions are being claimed, not methods of use which would have a "mode of operation". Groups I and III are hereby rejoined as a single group encompassing all pending claims for examination purposes.

Applicants make similar arguments as to the claims of Groups II and IV. However, since the claims of these Groups have all been canceled no decision thereon is required. Applicants have not traversed the election of species requirement which remains in effect.

DECISION

Applicants' petition under 37 CFR 1.144 is **GRANTED** for the reasons set forth above.

As applicants have replied to the last Office action, and the response is a complete response, the application will be forwarded to the examiner for further action not inconsistent with this decision.

Should there be any questions with respect to this decision, please contact William R. Dixon, Jr., by mail addressed to: Director, Technology Center 1600, Washington, D.C. 20231, or by telephone at (703)308-3824 or by facsimile transmission at (703) 305-7230.

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